UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,923	12/30/1999	ADNAN SHENNIB	ISM/012	7053

7590 08/12/2003

DONALD R GREENE
P O BOX 12995
SCOTTSDALE, AZ 852672995

EXAMINER
DABNEY, PHYLESHA LARVINIA

ART UNIT	PAPER NUMBER
2643	15

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/475,923	SHENNIB ET AL.	
	Examiner	Art Unit	
	Phylesha L Dabney	2643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-94* is/are pending in the application.

4a) Of the above claim(s) *82 and 94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-81 and 83-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 July 2003 has been entered.

Terminal Disclaimer

1. The terminal disclaimer filed on 29 July 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,137,889 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1, 3-9, 13-16, 19-30, 32-37, 39-53, 55-74, 77, 79, and 81, 83-93 are rejected under 35 U.S.C. 102(e) as being anticipated by Shennib et al (U.S. Patent No. 6,137,889).

Regarding claim 1, Shennib discloses a statically floating filament assembly (38) constructed and adapted to fit within the ear canal of an individual for contacting the tympanic membrane directly and imparting audible vibrations thereto, the filament assembly (38) being dynamically coupled to a stationary vibration force element (40) positioned in the ear canal at a distance from the tympanic membrane, the filament assembly comprising:

(a) a vibratory element (31) adapted to be laterally positioned when the filament assembly is fitted within the ear canal, and arranged to respond to dynamic forces imparted by the vibrational force element, and

(b) a vibrational shaft element (30) extending medially for transferring audible vibrations from the vibratory element (31) to the tympanic membrane when the filament assembly is fitted within the ear canal,

the filament assembly (38) dynamically coupled to the stationary force element so as to be statically floating and being freely movable within an operable range with respect to the vibration force element, thereby allowing individual adjustment and positioning of the filament assembly for contacting the tympanic membrane and imparting audible vibrations without exerting static forces thereto (see figures 5-11).

Regarding claim 3, Shennib discloses the vibrational shaft is radially flexible (col. 10 lines 30-43; col. 11 lines 3-7; col. 17 lines 4-11).

Regarding claim 4, Shennib discloses the length of the filament assembly is at least 6 mm (col. 10 lines 55-57 and col. 16 lines 57-62).

Regarding claim 5, Shennib discloses the diameter of the vibrational shaft element and the vibratory element (31) is less than 0.4mm (col. 16 line 57 thru col. 17 line 53).

Regarding claim 6, Shennib discloses the ratio of length of the filament assembly to diameter of the vibrational shaft element (col. 10 lines 55-57 and col. 16 line 57 thru col. 17 line 30).

Regarding claims 7 and 43, Shennib discloses the filament assembly (38) is separable from the vibrational force element (40) for placement and replacement therein (col. 9 line 53 thru col. 10 line 13).

Regarding claim 8, Shennib discloses the filament assembly weights less than 20 mg (col. 10 lines 63-65).

Regarding claims 9, 44, and 45, Shennib discloses the vibratory element (31) comprises a magnetic material (36, col. 9 lines 31-45), which vibrates in response to a magnetic field produced from the vibration force element (40).

Regarding claims 13 and 47, Shennib discloses a tympanic coupling element (31) adapted to contact the tympanic membrane for transferring the audible vibrations thereto.

Regarding claim 14, Shennib discloses the tympanic coupling element (31) is articulated with respect to the vibrational shaft element (30) via an articulation joint (col. 9 lines 31-45).

Regarding claims 15-16, Shennib discloses the articulation joint (col. 9 lines 31-45) comprises a rounded edge (37, ball) and a recess (36, socket) with magnetic attraction there between.

Regarding claim 19, Shennib discloses the vibrational shaft element comprises a rigid material selected form a group comprising metal and plastics (col. 17 lines 4-11).

Regarding claims 20 and 49, Shennib discloses the tympanic coupling element is removably attachable to the tympanic membrane by means providing a relatively weak adhesion force (col. 8 lines 48-65).

Regarding claims 21 and 50, Shennib discloses the relatively weak adhesion force means includes a layer of biocompatible agent between the tympanic coupling element and the tympanic membrane for providing adhesion there between (col. 8 lines 48-65).

Regarding claims 22 and 51, Shennib discloses the biocompatible agent is selected from a group comprising gel and oil(col. 8 lines 59-62).

Regarding claim 23, Shennib discloses the biocompatible agent is non-drying for providing long term adhesion between the tympanic coupling element (31) and the tympanic membrane (col. 8 lines 54-59).

Regarding claims 24 and 52, Shennib discloses the tympanic coupling element (31) is self-centering with respect to the umbo area of the tympanic membrane during attachment thereto (col. 10 lines 44-52).

Regarding claim 25, Shennib discloses the tympanic coupling element (31) is arranged and adapted for surgical attachment to one of either the tympanic membrane or malleus (col. 9 lines 7-17).

Regarding claims 26-27 and 53, Shennib discloses the tympanic coupling element (31) is umbrella shaped (col. 10 lines 44-53).

Regarding claims 28-29, Shennib discloses the tympanic coupling element (31) comprises a conforming surface selected from a group comprising silicone, rubber, and gel (col. 9 lines 1-6).

Regarding claim 30, Shennib discloses the tympanic coupling element is composed of oxygen permeable material (col. 9 lines 46-52).

Regarding claims 32 and 69, Shennib discloses the vibrational force element (40) comprises an electromagnetic coil (col. 11 line 57 thru col. 12 line 23).

Regarding claims 33 and 70, Shennib discloses the electromagnet coil (col. 11 line 57 thru col. 12 line 23) comprises an air-core (col. 18 lines 23-56) for accepting the filament assembly.

Regarding claims 34 and 71, Shennib discloses the vibration force element (40) comprises a vibrating element (41, 81) for directly vibrating the vibratory element (31) of the filament assembly.

Regarding claims 35-36 and 55-56, Shennib discloses the filament assembly conducts audible vibrations at least partially by means of axial and rocking motion (col. 11 lines 35-40).

Regarding claim 37, Shennib discloses the filament assembly comprises an elongated thin strip selected from a group comprising piezoelectric, piezomagnetic or magnetostrictive elements (col. 12 lines 29-33).

Regarding claims 39 and 79, Shennib discloses the filament assembly comprising lubricous means for minimizing contact friction of the filament assembly with the vibration force element (col. 8 line 53 col. 9 line 17).

Regarding claims 40 and 81, Shennib discloses the filament assembly comprising medication material selected form a group including anti-bacterial, anti-fungal, and anti-microbial agents (col. 8 line 53 thru col. 9 line 17).

Regarding 41, Shennib discloses a canal hearing device (50, 70) adapted for directly contacting the tympanic membrane and imparting audible vibrations thereto, comprising:

a floating filament assembly (38); a stationary vibration force element (40) positioned in the ear canal at a distance from the tympanic membrane, the filament assembly (38) dynamically coupled to the stationary force element so as to be statically floating thereto and responsive to dynamic forces imparted by the vibration force element on the filament assembly for movement freely within an operable range in at least one degree of freedom with respect to the vibration force element, thereby allowing individual adjustment and positioning of the filament assembly for contacting the tympanic membrane and imparting audible vibrations without exerting static forces thereto (see figures 5-11).

Regarding claim 42, see rejection of claims 5 and 6.

Regarding claim 46, see rejection of claim 34.

Regarding claim 48, see rejection of claims 14 and 15.

Regarding claim 57, Shennib discloses the hearing device including a retainer means (56).

Regarding claim 58, Shennib discloses the retainer means comprises one or more pairs of foldable wings (figures 13 and 14).

Regarding claim 59, Shennib discloses the retainer means (56) comprises a biocompatible adhesive (col. 12 lines 66-67).

Regarding claim 60, as shown in the figures, Shennib discloses a hearing aid constructed and adapted to be worn completely within the ear canal.

Regarding claim 61, as shown in the figures, Shennib disclose the hearing device (50) is constructed and adapted to be positioned substantially within the bony portion (13) of the ear canal.

Regarding claim 62, Shennib disclose the hearing device provides a highly energy efficient system to enable the hearing device to be operational in the ear canal of the wearer for a period exceeding two months (col. 14 lines 30-33 and also claim 47 of 6,137,889).

Regarding claim 63, Shennib discloses the hearing device including remote control means (col. 13 line 61 thru col. 14 line 12, and col. 15 lines 2-53).

Regarding claim 64, Shennib discloses the hearing device including a magnetically activated switch (91, 145), and wherein the remote control means (95, 140) comprises an external magnetic device (96, 98, 141-142).

Regarding claim 65, Shennib discloses the hearing device including a debris guard (57) for protecting the microphone (51).

Regarding claim 66, Shennib discloses the hearing device having a plurality of removable disposable elements including the filament assembly (38), a battery (54), an acoustically transparent guard (57), an acoustic screen (59), and a retainer (56).

Regarding claim 67, Shennib discloses the hearing device having an external fitting system connectable to the canal hearing device for conducting audiometric

evaluation, device programming and fitting prescription for subject wearing the hearing device (col. 14 lines 44-67).

Regarding claim 68, Shennib discloses the hearing device comprising a wireless receiver (71) for receiving wireless signals (97) representative of audio signals from an external audio transmitter, the hearing device being responsive to received wireless signals.

Regarding claim 72, Shennib discloses the vibrational force element comprises a shield (43, 56, 57, 69) for minimizing at least one electrical noise signal or magnetic noise signal.

Regarding claims 73 and 74, Shennib discloses the hearing device (50, 70) comprising means (43, 56, 57, 69) for rendering the hearing device substantially non-occlusive within the ear canal.

Regarding claim 77, Shennib discloses a means of manipulating the vibrational filament assembly for attachment to the tympanic membrane in corporation with probe tube and corresponding acoustic probe tube measurements (110).

Regarding claim 83, Shennib discloses a hearing device constructed and adapted to fit and be worn within the ear canal of a human subject for imparting audible vibrations to the tympanic membrane of the subject, comprising: a microphone (51); an amplifier (53); a vibration force element (40); and a vibrational filament assembly (30, 31), the vibrational filament assembly being essentially free floating within an operable range in at least one degree of freedom with respect to the vibration force element, thereby allowing individual adjustment and positioning of the vibrational filament

assembly for contacting the tympanic membrane and imparting audible vibrations without exerting essentially any static forces thereto.

Regarding claim 84, Shennib discloses the vibrational filament assembly (30, 31) comprising: an umbrella-shaped tympanic coupling element (31) for contacting and adhering to the tympanic membrane and conducting vibrations thereto; and a vibrational conductive shaft (30) articulated with the tympanic coupling element.

Regarding claim 85, see rejection of claim 41.

Regarding claim 86, see rejection of claim 47.

Regarding claim 87, see rejection of claim 49.

Regarding claim 88, see rejection of claim 50.

Regarding claim 89, Shennib discloses pre-coating the tympanic membrane with a liquid agent for adhering the tympanic coupling element (31) to the tympanic membrane (col. 8 lines 54-62).

Regarding claims 90-91, see rejection of claim 48.

Regarding claim 92, see rejection of claim 52.

Regarding claim 93, Shennib discloses a method of manipulating and attaching a floating vibrational filament assembly to the tympanic membrane, including dynamically coupling the floating vibrational filament assembly (30, 31) to a vibration force element (40), and performing the manipulating and attaching of the floating vibrational filament assembly to the tympanic membrane by means incorporating any direct visualization, optical fiber visualization and acoustic probe tube measurements (110).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

3. With respect to the 102(e) rejection above, as stated in the MPEP (section 804), the applicant needs to provide evidence that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4. For your convenience the arguments pertaining to the claims from the previous office action is listed below:

In response to the applicant's arguments presented on pages 5-7 of the amendment which includes: the filament assembly of the patent is not dynamically coupled to a stationary vibration force element and able to move relatively freely axially with respect to the vibration force element so that it produces substantially zero static pressure on the tympanic membrane, i.e. the filament assembly is statically floating (amendment: page 5 lines 21-25 and page 7 lines 3-5); the filament assembly of the patent is not freely movable within an operable range relative to a stationary vibration force element to impart audible vibrations without static forces on the tympanic membrane, within the meaning given of those terms in the specification (amendment: page 7 lines 4-7); and the filament assembly is firmly affixed to the force element. The examiner disagrees with the applicant's arguments for the following reasons:

a) With respect to the applicant's argument that filament assembly of the patent is not dynamically coupled to a stationary vibration force element and is not able to move relatively freely axially, i.e. an operable range, with respect to the vibration force element, the applicant's specification (09/475923: page 7 lines 23-25 and page 8 line 24

through page 9 line 7) states that dynamic coupling occurs when the coil produces a magnetic field which causes the filament assembly to conduct vibrations to the tympanic membrane. In view of these statements and the Shennib patent (Fig.8 and col. 12 lines 4-12), the examiner disagrees with the applicant's statements. Since the filament assembly (30, 31, 38; via the armature 81) is coupled to the stationary vibrational force element (40; housed within a specific location of the hearing aid) in such away that it does move in a push/pull, i.e. axial, and/or radial manner due to the alternating current conducting through the wires to the coil (83) which produces the magnetic field to cause the armature (81) to vibrate axially and/or radially which in turns causes the filament assembly to vibrate, then the filament assembly and the vibrational force element are in fact dynamically coupled.

b) With respect to the applicant's argument that the filament assembly of the patent is not able to move relatively freely axially *within an operable range*, with respect to the vibration force element so that it produces substantially zero static pressure on the tympanic membrane, i.e. the filament assembly is not statically floating, the applicant's specification ((09/475923: page 18 lines 1-8) states that "dynamic coupling...eliminate[s] static forces...." He also states that "Dynamic coupling...eliminate[s] both static and transient pressures...." As stated in section (a) above, the Shennib patent teaches a dynamically coupled system. Furthermore, the Shennib patent states that the filament assembly exerts minimal static force, i.e. *substantially* zero static pressure caused by static forces applied to the tympanic membrane (col. 9 lines 18-30); therefore, the filament assembly is statically floating. Therefore, the examiner disagrees with the applicant's arguments.

c) With respect to the applicant's argument that the filament assembly of the patent is not statically floating because it is firmly affixed to the force element, the examiner agrees with the applicant's argument that the assembly is firmly affixed to the force element (because the filament assembly is coupled to the armature (81) which is part of the vibratory force element). but the examiner does not agree that the assembly is not statically floating. Since the applicant's specification (page 8 line 17-23) and the arguments presented in the amendment (page 5 lines 21-24) states that if the filament assembly is supported by the tympanic membrane and dynamically coupled to the vibration force element and freely movable within an operable range, then the filament assembly is statically floating. The Shennib patent teaches that adhesion (32) is applied to the tympanic membrane for securing the filament assembly in a stationary position. In addition, as stated in section (a) above, the Shennib patent teaches a dynamically coupled system able to move freely in an operable range with respect to the vibration force element. Furthermore, the claims do not stipulate that the filament assembly and force element cannot be affixed to one another. The claims stipulate that the filament assembly must be dynamically coupled and able to statically float with respect to the force element.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued

examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phylesha L Dabney whose telephone number is 703-306-5415. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, Fridays 8:30-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Kuntz can be reached on 703-305-4708. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9314 for regular communications and 703-872-9314 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-4700.

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9314, for formal communications intended for entry and for informal or draft communications, please label "Proposed" or "Draft" when submitting an informal amendment.

(703) 306-0377, for customer service questions.

Hand-delivered responses should be brought to Crystal Park II, 2121 Crystal Drive, Arlington, VA., Sixth Floor (Receptionist).

PLD
August 11, 2003

CURTIS KUNTZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2600